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(Adopted November 1, 1989)

11-9-100 GENERAL

11-9-101 Description: The purpose of this rule is to control ethylene oxide and NPOC emissions from sterilization operations. (Amended August 1, 1990; May 6, 1992)

11-9-102 Exemption, Users of Small Quantities of Ethylene Oxide: The provisions of this Rule do not apply if the facility-wide usage of ethylene oxide is less than 25 pounds per year. (Amended August 1, 1990)

11-9-103 Exemption, Ampule/Liner Bag Sterilizers: The provisions of this Rule do not apply to sterilizers of the liner-bag design using ampules of ethylene oxide, provided that no more than one ounce is used in any one charge, and no more than 25 pounds is used annually. (Amended August 1, 1990)

11-9-200 DEFINITIONS

11-9-201 Aeration: Any process during which residual ethylene oxide is removed from sterilized materials. (Amended August 1, 1990; May 6, 1992)

11-9-202 Aeration-only Facility: A facility which performs aeration on materials which have been sterilized with ethylene oxide at another facility. (Amended August 1, 1990)

11-9-203 Aerator: Any device in which aeration occurs.
(Amended August 1, 1990; May 6, 1992)

11-9-204 Aerator Emissions: All ethylene oxide or NPOC contaminated air which is removed from an aerator. (Adopted August 1, 1990; Amended May 6, 1992)

11-9-205 Complete Recovery System: Any sterilizer emission abatement equipment designed to recapture all sterilant gases. (Adopted May 6, 1992)

11-9-206 Leak-free: Where the concentration of sterilant gas, measured 1 centimeter away from any portion of the sterilizer system, is less than 10 ppm, as determined by a portable flame ionization detector calibrated with methane, or an equivalent method approved by the Air Pollution Control Officer and in accordance with CARB test method 21. (Adopted August 1, 1990; Amended and Renumbered May 6, 1992)

11-9-207 Non-Precursor Organic Compound (NPOC):

methylene chloride
chloropentafluoroethane (CFC-115)
1,1,1-trichloroethane
2-chloro-1,1,1,2-tetrafluoroethane (HCFC-124)
1,1,2-trichlorotrifluoroethane (CFC-13)
pentafluoroethane (HCFC-125)
trichlorofluoromethane (CFC-11)
1,1,2,2-tetrafluoroethane (HFC-134)
dichlorodifluoromethane (CFC-12)
1,1,1-trifluoroethane (HFC-143a)
dichlorotetrafluoroethane (CFC-114)
1,1-difluoroethane (HFC-152a)
chlorodifluoromethane (CFC-22)
trifluoromethane (CFC-23)
cyclic, branched or linear completely fluorinated alkanes
cyclic, branched or linear completely fluorinated saturated ethers
cyclic, branched or linear completely fluorinated saturated tertiary amines
saturated perfluorocarbons with sulfur bonding to carbon and/or fluorine

(Adopted May 6, 1992)

11-9-208 Sterilizer: A chamber that contains ethylene oxide (EtO) in any quantity or concentration for the purpose of destroying bacteria or viruses.

208.1 Hospital Sterilizer: A sterilizer located in a hospital, medical clinic, dental clinic, veterinary clinic, or any other medical facility.

208.2 Commercial Sterilizer: All sterilizers except hospital sterilizers.

(Adopted May 6, 1992)

11-9-209 Sterilizer Cycle: The process which begins when ethylene oxide is introduced into the sterilizer and concludes after all ethylene oxide removal and aeration is complete.
(Adopted August 1, 1990; Amended May 6, 1992)

11-9-210 Sterilizer Emissions: All ethylene oxide or NPOC contaminated air which is removed from a sterilizer. (Adopted August 1, 1990; Amended May 6, 1992)

11-9-211 Vacuum Pump: Any mechanical device or devices used to remove the sterilant gas during the sterilizer cycle.

(Amended and Renumbered August 1, 1990; Amended May 6, 1992)

11-9-300 STANDARDS

11-9-301 Commercial Sterilizers: A person shall not operate a commercial ethylene oxide sterilizer unless emissions of ethylene oxide are controlled as follows:

Facility-Wide EtO Usage (lb/Year)	Sterilizer EtO Emission Control Required	Aerator EtO Emission Control Required	Notes
Less than 600	99%	--	--
600 to 5000	99.9%	95%	--
Over 5000	99.9%	99%	If vented, sterilizer door seal must vented to abator

All abatement devices shall be approved by the APCO prior to installation, and such abatement devices shall be sized, installed, operated, and maintained according to good engineering practices. (Amended August 1, 1990; May 6, 1992)

11-9-302 Hospital Sterilizers: A person shall not operate a hospital ethylene oxide sterilizer unless emissions of ethylene oxide are controlled as follows:

Sterilizer Chamber Volume (Cu Ft)	Sterilizer EtO Emission Control Required	Aerator EtO Emission Control Required
Less than 10	99%	--
Greater than 10	99.9%	95%

All abatement devices shall be approved by the APCO prior to installation. Such abatement devices shall be sized, installed, operated, and maintained according to good engineering practices. (Adopted August 1, 1990; Amended May 6, 1992)

11-9-303 All Sterilizers: A person shall not operate an ethylene oxide sterilizer unless all NPOC emissions from the sterilizer and aerator are reduced 95% by weight.

(Adopted May 6, 1992)

11-9-304 Aeration Only Facilities: A person shall not operate an Aerator unless all EtO emissions from the Aerator are reduced 95% by weight. (Adopted May 6, 1992)

11-9-310 Vacuum Pump: A person shall not operate an ethylene oxide sterilization chamber unless the seal fluid in the vacuum pump is recirculated or the chamber evacuation equipment is otherwise designed such that no ethylene oxide is released.

(Adopted August 1, 1990; Amended May 6, 1992)

11-9-320 Detection Limit: If the concentration of ethylene oxide measured in the outlet of the abatement device is below 0.2 parts per million, the facility shall be considered to be in compliance with section 11-9-301 or 11-9-302.

(Adopted August 1, 1990; Amended May 6, 1992)

11-9-330 Continuous Control: Any sterilizer exhaust stream or aerator exhaust stream subject to an abatement efficiency requirement in 11-9-301 or 11-9-302 shall be continuously vented to, and shall not bypass, the abatement device.

(Adopted August 1, 1990)

11-9-340 Leak-free Operation: A person shall not operate an ethylene oxide sterilization chamber or aerator unless all systems are leak-free as defined by 11-9-206.

(Adopted August 1, 1990; Amended May 6, 1992)

11-9-400 ADMINISTRATIVE REQUIREMENTS

11-9-401 Deleted August 1, 1990

11-9-402 Effective Dates:

Sections 11-9-301, 11-9-302, 11-9-304, 11-9-310, 11-9-320, 11-9-330, and 11-9-340 are effective August 1, 1993.

Section 11-9-303 is effective August 1, 1993, unless the District has issued an Authority To Construct before January 1, 1992, in which case the effective date is August 1, 1995. (Amended August 1, 1990; May 6, 1992)

11-9-403 Initial Demonstration of Compliance: Any person subject to Section 11-9-301 or 11-9-302 shall, no later than 60 days from the effective date, perform a source test to determine compliance, as specified in Section 11-9-601.

(Amended August 1, 1990)

11-9-404 Permit to Operate: A person shall not operate an ethylene oxide sterilizer subject to this Rule without obtaining a Permit to Operate. (Amended August 1, 1990)

11-9-500 MONITORING AND RECORDS

11-9-501 Record Keeping: Any person subject to this rule, or subject to the exemption in Section 11-9-102, shall (1) maintain a log which notes the date and time of each sterilizer operation cycle (such records shall be retained and made available for District inspection), and (2) keep records of all ethylene oxide and NPOC usage as determined in 11-9-603 (which shall be made available for District inspection).

(Amended August 1, 1990; May 6, 1992)

11-9-502 Operation and Maintenance: Any person subject to this Rule shall submit records that the APCO deems necessary to demonstrate proper operation and maintenance of emission control equipment. (Amended August 1, 1990)

11-9-600 MANUAL OF PROCEDURES

11-9-601 Determination of Emissions For Non-Complete Recovery Systems: Emissions of ethylene oxide both upstream and downstream of abatement equipment shall be measured as prescribed in CARB Test Method 431.

601.1 The test on an abatement device for sterilizer exhaust stream shall be run with a typical load in the sterilizer, as approved by the Air Pollution Control Officer.

601.2 The test on an abatement device for an aerator exhaust stream shall be run with a typical load in the aerator, as approved by the Air Pollution Control Officer.

601.3 The inlet and outlet of the abatement device shall be sampled simultaneously during testing to measure the abatement efficiency.

601.4 The efficiency of each abatement device shall be determined under conditions of maximum ethylene oxide and NPOC mass flow to the device, under normal operating conditions. To measure the abatement efficiency of the abatement device on the sterilizer exhaust stream, sampling shall be done during the entire duration of the first sterilizer evacuation after ethylene oxide has been introduced. To measure the abatement efficiency of the abatement device on an aerator exhaust stream with a constant air flow, sampling shall be done during a period of at least 60 minutes, starting 15 minutes after aeration begins. To measure the abatement efficiency of the abatement device on an aerator exhaust stream with a non-constant air flow, sampling shall be done during the entire duration of the first aerator evacuation after aeration begins.

601.5 There shall be no dilution of the air stream between the inlet and outlet test points during testing.

601.6 NPOC emissions shall be measured both upstream and downstream of the abatement device following a procedure deemed acceptable by the APCO.

(Amended August 1, 1990; May 6, 1992)

11-9-602 Determination of Emissions for Total Recovery Systems: Systems that recover all sterilant gases shall have their emissions tested both upstream and downstream of the recovery unit as proscribed in the manual of procedures volume IV, ST-45, or by an equivalent method deemed acceptable by the APCO. (Adopted May 6, 1992).

~~**11-9-603 Determination of Sterilant Gas Usage:** The quantity of sterilant gas used for each sterilizer cycle shall be determined as proscribed in the manual of procedures volume IV, ST-45, or by an equivalent method deemed acceptable by the APCO.~~

(Adopted May 6, 1992)